

**DE-1495**

**REMARKS**

The last office action has been carefully considered.

**35 USC § 112 Rejections**

Claims 1 and 13 have been amended herein and now are believed to fully comply with 35 USC 112. Claims 1 and 13 now recite in pertinent part that the heat shrink plastic cover forms a seal. It is respectfully submitted that this amendatory language overcomes the 35 USC 112 first and second paragraph rejections. Support for this feature can be found on page 3, bottom paragraph and page 4, lines 5-6 and bottom paragraph. It is therefore respectfully requested that these rejections be withdrawn.

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**Claim Rejections under 35 US 102 and 35 US 103  
As to Key (US 6, 385,878**

The claimed invention as recited in independent claims 1 and 13 1 recites in pertinent part a safety seal system for maintaining alert medications prior to use or administration and a heat-shrink plastic cover, a seal and other distinguishing characteristics on the seal to differentiate a high-alert medication to a person preparing the medical container at point of use or administration to prevent the container from being mistaken for a different container. In particular the claimed invention provides a seal formed by a plastic cover that covers a substantial portion of the container and wherein warning statements and other distinguishing characteristics are located on the seal so that in order to remove the seal from the container the preparer is forced to look at the warning statements and other distinguishing characteristics on the seal and thus be alerted to the high alert medication in the container which seal is being opened. The fact that the perforation lines are located on portions of the seal that require the visual attention of the preparer results in the preparer looking at the warning statement and other distinguishing characteristics during the removal of the seal by pulling the seal along the perforated lines and thus alerting the preparer to the high alert medication inside the container.

The patent to Key relates to a tamper-evident labeling system that rotates the label 360 degrees to provide additional product labeling space and at the same time provide a tamper-evident seal in order that consumers can identify if the contents of the container were altered after the manufacturer produced and sealed the product.

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In Keyes a standard labeling occurs on the container and not a high alert warning on the seal. Further since Keyes is directed toward a rotating label system, the disclosure of Keyes teaches away from a warning statement that is essentially "in the face "of the preparer as the label in Keyes can rotate rather than being placed in a position where when the seal is removed the warning statement is in front of the eyes of the preparer.

Key does not address providing multiple alerts visual, tactile and functional to the provider in the process of medication administration and drawing the provider's special attention to these products at the time the seal is being removed and the warning alerts are

Accordingly it is respectfully submitted that claims 1 and 13 and the rest of the claims in the present application, for the aforementioned reasons are not taught or suggested by Key, either alone or in combination with Novacek, et al. It is therefore respectfully required that the rejections be withdrawn.

In view of the amendments and arguments presented herein, it is respectfully requested that the claims remaining in the present application be passed to issue.

Respectfully submitted

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**CERTIFICATE OF MAILING**

I hereby certify that this AMENDMENT is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June ,  
2006.

\_\_\_\_\_ (Typed or printed name of person mailing paper or fee)  
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